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***Via ECF and Courtesy Copy via Hand Delivery***

Honorable Garrett E. Brown, U.S.D.J.
United States District Court
Clarkson S. Fisher Federal Building
402 E. State Street, Courtroom 4E
Trenton, New Jersey 08608

***Re: King Pharmaceuticals, Inc. v. Sandoz Inc.***
***Civil Action No. 08-5974 (GEB) (DEA)***

Dear Chief Judge Brown:

We, together with Cohen Pontani Lieberman & Pavane LLP, represent Sandoz in the referenced action. We hereby move that those portions of two of plaintiffs' May 27, 2010 expert reports that concern new infringement contentions be stricken, and that plaintiffs be precluded from relying upon infringement contentions disclosed to Sandoz for the first time in those reports. Specifically, plaintiffs identified only Sandoz's package insert for metaxalone in their infringement contentions, and now rely on eight additional Sandoz package inserts for other drug products. Plaintiffs have not even sought an order of this Court permitting amendment of their July 13, 2009 infringement contentions. Sandoz has been prejudiced by this late disclosure because the disclosure comes late in the case and close to trial, and after Sandoz already has served its expert report on patent invalidity, thus preventing a Sandoz expert from considering how plaintiffs' new infringement contentions may affect the invalidity of the '566 patent.

As this Court noted in a prior opinion in this case (D.E. 125 opinion, filed May 20, 2010), the Local Patent Rules "exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases. The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." Id. at page 7 (citations omitted). None of these goals is met by the plaintiffs' conduct here at issue.

**A. Plaintiffs' Infringement Contentions Pursuant to the Local Patent Rules**

The Pretrial Scheduling Order (D.E. 20, filed April 27, 2009) required plaintiffs to provide their Disclosure of Asserted Claims and Infringement Contentions by July 10, 2009. Plaintiffs were required to include in that disclosure a specific description and application of every Sandoz instrumentality concerning plaintiffs' infringement contentions. Id., paras. 4(b) and 4(c).

Plaintiffs served Plaintiffs' Preliminary Disclosure of Asserted Claims and Infringement Contentions ("Infringement Contentions") on Sandoz on July 13, 2009. Exhibit 1. In these Infringement Contentions, plaintiffs disclose that the only package inserts on which they rely in support of their infringement claim are the metaxalone package inserts of King (for King's Skelaxin® brand of metaxalone) and Sandoz (for Sandoz's generic metaxalone tablets).

In their July 13, 2009 Infringement Contentions, plaintiffs define "Sandoz's ANDA Products" as Sandoz's generic metaxalone drug products:

> [T]he product Plaintiffs contend is being used according to the methods claimed in the ['566 patent] is Sandoz's ANDA Products distributed with labeling that is identical in substance to the current Skelaxin® product labeling.

Infringement Contentions (Exhibit 1), page 4 (emphasis added).

Exemplary of Plaintiffs' July 13, 2009 Infringement Contentions, which disclose reliance on Sandoz's metaxalone package insert and no Sandoz package insert for any other Sandoz drug product, are such statements as:

> If Sandoz's ANDA products are approved by the FDA, patients will follow the instructions provided by Sandoz and use Sandoz's ANDA products for the treatment of medical conditions, including musculoskeletal conditions.

Infringement Contentions (Exhibit 1) at page 2 of Exhibit A thereto.

> Medical care workers, pharmacists and patients are the intended targets for Sandoz's ANDA products, and they will read, review and rely upon labeling information distributed with that product when making decisions about the safe and effective administration of that product for the treatment of any condition.

Infringement Contentions (Exhibit 1) at page 5 of Exhibit A thereto.

> Affirmative acts that will induce these infringements include the manufacture, distribution and sale of Sandoz's ANDA products with product labeling indicating that administration of metaxalone with a substance that affects activity of a cytochrome p450 isozyme can affect plasma concentration, safety, efficacy of any combination thereof of metaxalone, the substance or both.

Infringement Contentions (Exhibit 1) at page 6 of Exhibit A thereto.

> Affirmative acts that will induce these infringements include the manufacture, distribution and sale of Sandoz's ANDA products with product labeling with cautions regarding administration of metaxalone with substances that affect activity of a cytochrome p450 isozyme referred to in the labeling for Sandoz's ANDA products that are active agents with a narrow therapeutic index.

Infringement Contentions (Exhibit 1) at page 7 of Exhibit A thereto.

There are many similar statements included in Exhibit A to Plaintiffs' July 13, 2009 Infringement Contentions, all showing that no Sandoz package insert for any product other than Sandoz's metaxalone product was being relied upon by plaintiffs in support of their Infringement Contentions.

**B. Plaintiffs' New Infringement Contentions**

Sandoz first learned of plaintiffs' new infringement contentions on May 27, 2010, when plaintiffs served the expert reports of Drs. Elia, Barber, Guengerich and Gusmorino on Sandoz. In plaintiffs' expert reports, plaintiffs for the first time also identify and rely upon Sandoz package inserts for eight additional Sandoz generic drug products as a basis for arguing infringement. [1] In doing so, plaintiffs raise the new contention that Sandoz's infringement of the '566 patent arises from the combination of Sandoz's metaxalone package insert together with other Sandoz package inserts for other Sandoz drug products,[2] whereas in plaintiffs' July 13, 2009 Infringement Contentions and at all times prior to plaintiffs' expert reports served on May 27, 2010, plaintiffs relied solely on Sandoz's package insert for metaxalone as a basis for infringement.

**C. Plaintiffs Never Sought to Amend Their Infringement Contentions**

"Amendment of the Infringement Contentions or the Invalidity Contentions may be made by order of the Court upon a timely application and showing of good cause." Local Patent Rule 3.7. Plaintiffs have not made any such application, much less received an appropriate order. There is no basis for plaintiffs' experts opining on new infringement contentions.

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[1] The eight new Sandoz package inserts that plaintiffs rely on are those for Sandoz's generic drug products alprazolam, amiodarone, bicalutamide, bupropion, clomipramine, fentanyl, fluvoxamine and perphenazine.

[2] *E.g.*, Expert Report of Michael E. Elia, M.D. (Exhibit 2) at para. 24, pages 7-8 and para. 41, page 13; Expert Report of F. Alan Barber, M.D. (Exhibit 3) at paras. 23-31, pages 8-13; para. 35, page 14; para. 39, pages 14-15; paras. 41 and 42, page 15; paras. 49-50, page 17; paras. 58-59, pages 19-20; para. 61, page 20; paras. 63-64, page 21; para. 65, pages 21-22; and paras. 67-82, pages 22-26.

**D. Sandoz Would Be Substantially Prejudiced if Plaintiffs' Were Allowed to Rely on Their New Infringement Contentions**

The prejudice to Sandoz if plaintiffs are permitted to rely on their new infringement contentions is palpable. Had plaintiffs disclosed their new infringement contentions as required by the Local Patent Rules, i.e., on July 13, 2009, Sandoz, at that time, would have sought leave to amend its invalidity contentions to assert additional theories of invalidity. Sandoz also would have addressed these infringement contentions in its expert report on invalidity, but that was impossible, because Sandoz was required to serve that report before plaintiffs' new infringement contentions were disclosed. If plaintiffs' new infringement contentions are allowed, Sandoz will have insufficient time to address them in the Sandoz's rebuttal reports due next week and will have insufficient time to seek out new experts to address these new contentions.

**E. Conclusion**

Those portions of the expert reports of Dr. Elia and Dr. Barber that rely on plaintiffs' new infringement contentions should be stricken. These portions include the following: Expert Report of Michael E. Elia, M.D. (Exhibit 2) at para. 24, pages 7-8 and para. 41, page 13; Expert Report of F. Alan Barber, M.D. (Exhibit 3) at paras. 23-31, pages 8-13; para. 35, page 14; para. 39, pages 14-15; paras. 41 and 42, page 15; paras. 49-50, page 17; paras. 58-59, pages 19-20; para. 61, page 20; paras. 63-64, page 21; para. 65, pages 21-22; and paras. 67-82, pages 22-26. Plaintiffs also should be precluded from relying upon any Sandoz package insert other that the Sandoz package insert for metaxalone, the only Sandoz package insert identified in plaintiffs' July 13, 2009 Infringement Contentions.

Respectfully submitted,

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